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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/823,089	04/12/2004	Signe Erickson Varner	56086CON2 (71699)	3168

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EXAMINER	
HUH, BENJAMIN	
ART UNIT	**PAPER NUMBER**
3767	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/823,089	VARNER ET AL.	
	Examiner	Art Unit	
	Benjamin Huh	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 February 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *82-91 and 103-114* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *82-91 and 103-114* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 82-89, 91, 103-111, & 114 are rejected under 35 U.S.C. 103(a) as being unpatentable by Rosenman et al (US Patent No. 6478776 B1) in view of Rosenwald (US Patent No. 4678466). The Rosenman et al reference discloses the method for treating a patient comprising providing a delivery device comprising a helical, substantially Z-shaped, body member 12 having at least five deviations from a linear path and that has a shape other than a substantially C-configuration; and inserting into a patient the device whereby the body member resides in the patient and a therapeutic substance is administered to the patient via the body member, wherein the device is inserted through an incision created by the device, and wherein the cap element 56 abuts the incision from within the tissue and is fully capable of stabilizing the device due to it's size and shape, wherein the extra element inherently adds to the stability of the device, see abstract, col. 3 line 67 – col. 4 line 32, col. 5 lines 40 – col. 12 line 23, figures 4-5 & 8-19. Now even though Rosenman does not explicitly disclose that the device is inserted into the ear and resides in the patient ear attention is directed to

Rosenwald. The Rosenwald reference teaches the use of a drug delivery device that can be inserted in multiple areas such as the eye or the ear in order to provide medication to the desired location, see col. 9 lines 12-21. therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to utlize the device of Rosenman to treat a patient by administering a therapeutic substance to the patient via the device in any desired location for proper treatment.

With respect to claims 83-85, wherein the device body member can be seen to have at least five deviations from a linear path in figures 4-5.

With respect to claims 86-87, wherein the device body comprises a helical shape and has a substantially Z-shape in figures 4-5 & 8-19.

With respect to claims 88-89, wherein the body member comprises a polymer and comprises a therapeutic substance that can be delivered to the patient, see col. 10 lines 21-36 & col. 15 line 9 – col. 16 line 35.

With respect to claim 91, wherein the device length is about 1.5 cm or less, see col. 9 lines 31-37.

With respect to claim 105, wherein the device is twisted, see claim 1 Rosenman.

With respect to claims 108-111, see para [0038] & [0103], and wherein the use of various biodegradable polymers in implants is well known.

With respect to claim 114, wherein it would be an obvious to one of ordinary skill in the art at the time of the invention to modify the device of Rosenman to increase the size of the cap in order to more easily grip the head and for further stabilization of the device, also see MPEP 2144.04.

Claims 82-89, 91, & 103-114 are rejected under 35 U.S.C. 102(b) as being anticipated by Altman (US Patent No. 5551427) in view of Rosenwald (US Patent No. 4678466) or Dinius et al (US Patent No. 4451254) or Theeuwes et al (US Patent No. 4014334). The Altman reference discloses in figures 7-11 an implantable drug delivery device comprising a non-linear shaped body member 46 having at least two deviations from a linear path and that has a shape other than a substantially C-configuration and that is implanted within a patient to deliver a drug substance to the patient via the body member; and a cap element 54 that abuts an incision, seen as abutting the incision from within the tissue, through which the device is inserted to stabilize the device once implanted, wherein the cap is seen to stabilize the device through the fact that it will help anchor the device, also wherein the cap is seen to be fully capable of mating against an ear due to it's size, shape, and ability to work in the environment, see abstract , figures cited above, and col. 9 line 52 – col. 11 line 67. Now even though Altman does not explicitly disclose that the device is inserted into the ear and resides in the patient ear attention is directed to Rosenwald or Dinius or Theeuwes. The Rosenwald and Dinius and Theeuwes references teach the use of a drug delivery device that can be inserted in multiple areas such as the eye or the ear in order to provide medication to the desired location. Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to utilize the device of Altman in other areas such as the ear to treat a patient by administering a therapeutic substance to the patient via the device for proper treatment.

With respect to claims 108-113, see Altman col. 5 lines 15-25, col. 10 lines 25-42, also wherein the use of different biodegradable polymers is well known in the art.

Claim 90 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenman et al (US Patent No. 6478776 B1) in view of Rosenwald as applied above and further in view of Johnson (US Patent No. 5972027). Now even though Rosenman does not explicitly disclose the device comprising a shape memory material attention is directed to Johnson. The Johnson reference teaches an implantable drug delivery device with a non-linear shaped body member that can be made of nitinol, a very well known shape memory alloy of nickel-titanium, see col. 2 lines 39-56. Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to modify the device and use of Rosenman to utilize the teachings of Johnson to comprise the device of a shape memory material in order to provide a bio-compatible and strong device.

Claim 90 is rejected under 35 U.S.C. 103(a) as being unpatentable over Altman (US Patent No. 5551427) in view of Rosenwald (US Patent No. 4678466) or Dinius et al (US Patent No. 4451254) or Theeuwes et al (US Patent No. 4014334) as applied above and further in view of Johnson (US Patent No. 5972027). Now even though Altman does not explicitly disclose the device comprising a shape memory material attention is directed to Johnson. The Johnson reference teaches an implantable drug delivery device with a non-linear shaped body member that can be made of nitinol, a very well known shape memory alloy of nickel-titanium, see col. 2 lines 39-56. Therefore, it would

be obvious to one of ordinary skill in the art at the time of the invention to modify the device and use of Altman to utilize the teachings of Johnson to comprise the device of a shape memory material in order to provide a bio-compatible and strong device.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 82-91 & 103-114 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 83-110 & 117-120 of copending Application No. 10/740698. Although the conflicting claims are not identical, they are not patentably distinct from each other because both set of claims recite a method for treating a patient comprising a delivery device comprising a non-linear shaped body member with at least two deviations from a linear path and a cap

that abuts an incision to stabilize the device, inserting the device into a patient, and wherein a therapeutic substance is administered to the patient via the body member, and wherein it would be obvious to insert the implant where desired and that the shape of the body member can be a shape other than a substantially C-configuration.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's arguments filed 2/20/07 have been fully considered but they are not persuasive.

Applicant argues that Rosenman in view of Rosenwald fails to teach or suggest a device for insertion into the ear through an incision and a cap member that abuts an incision through which the device is inserted for stabilizing the device once it is implanted, the examiner disagrees. The Rosenwald reference is utilized to disclose that implants are often utilized in several different areas such that an implant could be utilized in the eye, ear, heart, etc. Implants are utilized for their controlled therapeutic release delivery abilities and therefore the location of the implants can be changed. Also, wherein Rosenwald explicitly states that an implant can be placed in the ear. Also, wherein the Rosenman reference suggests the device to be inserted through an incision, the incision being the one made by the device cutting into the desired location itself. If the applicant wishes to claim that there is a separate incision made before the device is inserted, the applicant should amend the claims to explicitly state those

limitations. Last, due to the size, shape, and ability of the cap of the invention, the cap would inherently stabilize the device once it is implanted and would abut the incision at some point since the device is twisted all the way into the desired location.

The new grounds of rejection are also entered due to the amendments to the claims as well as to the newly added claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin Huh whose telephone number is 571-272-8208. The examiner can normally be reached on M-F: 9:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BHH

BHH

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

Kevin C. Sirmons